

## **REMARKS**

Claims 1-85 are pending and under consideration in this Office action.

### **The Restriction Requirement**

The Office action states that this application contains claims directed to the following patentably distinct species of the claimed invention: 1) sorbitol or non-crystallizing sorbitol 2) maltitol 3) glycerin and 4) polyethylene glycol.

As required by the Examiner, in accordance with 35 U.S.C. § 121, applicant hereby elects as the single disclosed species for prosecution on the merits, species 1) sorbitol or non-crystallizing sorbitol. Applicant believes that all pending claims are readable on this elected species.

Applicant understands, however, that upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

### **The Amendment**

By this amendment, Claims 4 and 25 have been canceled, and new Claims 86-99 have been added, leaving Claims 1-3, 5-24 and 26-99 pending, all of which are still under consideration.

Applicant has amended the claims to point out more clearly that which the inventors consider to be their invention and to add claims to embodiments of particular interest. Thus,

independent Claims 1, 24, 46, 62, 76 and 84 have been amended, and the only new independent claim (Claim 86) has been written, to specify that the kappa carrageenan of the recited compositions is present “in an amount less than 100% by weight of the iota carrageenan” in those compositions. Support for this amendment provided, for instance, in original dependent Claims 4 and 25, now cancelled as redundant, in original Claims 5 and 26, now amended to delete this recitation as redundant, and in the specification, for example, at page 8, lines 16-18.

Claims 70-72 have been amended to clarify the antecedent basis to the parent method claims, by reciting that the subject ribbon or uniform dispersion was “made by the method of” the respective parent claims.

Claim 77 has been clarified by specifying that the components are “pre-mixed before adding them to the extruder”.

New Claims 86-88 have been added to claim a film-forming composition comprising from about 80% to about 95% by weight of solids and the remainder being about 20% to about 5% water, wherein the solids comprise iota carrageenan, kappa carrageenan in an amount less than 100% of the amount of the iota carrageenan, a bulking agent, and a plasticizer, various recited amounts. New Claim 88, dependent from Claim 86, specifies a capsule which comprises the film-forming composition of Claim 86, whereas Claim 89 is drawn to the capsule of Claim 88, wherein the capsule is an encapsulated dosage form having a shell that comprises the film-forming composition, and the encapsulated dosage form is selected from a softgel dosage form and a caplet dosage form. Support for these embodiments of the invention is provided in the specification, for instance, at page 16, lines 5-16 [048] (solids contents of compositions in capsules) and at page 5, lines 1-23 [013]-[017] (encapsulated, softgel and caplet dosage forms).

Further, Claims 90-92 are drawn to compositions, ultimately of Claim 86, comprising the specified plasticizers (Claim 90) or bulking agents (Claims 91 and 92), as recited in original Claims 15 and 13-14, respectively. Dependent Claims 94-99, directed to 94 film-forming compositions of Claims 1 and 24, in the form of a uniform dispersion in the shape of a film, ribbon, sheet or tube, and further, wherein the uniform dispersion has a solids content in the range of about 40% to about 90% by weight, are supported, for instance, by original Claims 44, 45 and 54, and in the specification, for example, at page 12, lines 15-17 [039].

Applicant believes that all pending claims, including all newly added claims, readable on the species elected pursuant to the above restriction requirement.

### **CONCLUSION**

In view of the foregoing, applicant believes that the present case is in condition for allowance and respectfully request examination on the merits and early notice to that effect. If any issues remain to be addressed in this matter, which might be resolved by discussion, the Examiner is respectfully requested to call applicant's undersigned counsel at the number indicated below.

Respectfully submitted,

WOMBLE CARLYLE SANDRIDGE & RICE



Paul C. Kimball  
Registration No. 34,641

P.O. Box 7037  
Atlanta, GA 30357-0037  
Telephone No. (202) 857-4426  
Facsimile No. (202) 261-0045

**MARKED UP COPY OF THE CLAIMS**

1. (Amended) A film-forming composition comprising:
  - a) iota carrageenan in an amount of from about 1% to about 15% by weight of the composition;
  - b) kappa carrageenan in an amount less than 100% by weight of the iota carrageenan;
  - c) a bulking agent, wherein the ratio of bulking agent to the combined total of iota and kappa carrageenan is from about 1:1 to about 20:1;
  - d) a plasticizer in an amount of from about 10% to about 50% by weight of the composition; and
  - e) water.
5. (Amended) The composition of claim 1, wherein [the kappa carrageenan is present in an amount of less than or equal to about 100% by weight of iota carrageenan present in the composition, and wherein] the total amount of all carrageenan is less than or equal to about 20% by weight of the composition.
24. (Amended) A film-forming composition comprising:
  - a) iota carrageenan in an amount of from about 1% to about 15% by weight of the composition;
  - b) kappa carrageenan in an amount less than 100% by weight of the iota carrageenan;
  - c) a bulking agent in an amount of from about 10% to about 60% by weight of the composition;
  - d) a plasticizer in an amount of from about 10% to about 50% by weight of the composition; and

e) water.

26. (Amended) The composition of claim 24, wherein [the kappa carrageenan is present in an amount of less than or equal to about 100% by weight of iota carrageenan present in the composition, and wherein] the total amount of all carrageenan is less than or equal to about 20% by weight of the composition.

46. (Amended) A method for preparing a film-forming composition comprising:

a) mixing iota carrageenan in an amount of from about 1% to about 15% by weight of the composition, kappa carrageenan in an amount less than 100% by weight of the iota carrageenan and a bulking agent in a ratio of bulking agent to total carrageenan of from about 1:1 to about 20:1 to form a dry mixture;

b) adding a plasticizer to the dry mixture;

c) adding water to the dry mixture to form a dispersion; and

d) heating and mixing the composition to form a uniform dispersion.

62. (Amended) A method for preparing a film-forming composition comprising:

a) mixing iota carrageenan in an amount of from about 1% to about 15% by weight of the composition, kappa carrageenan in an amount less than 100% by weight of the iota carrageenan and a bulking agent in a ratio of bulking agent to total carrageenan of from about 1:1 to about 20:1 to form a dry mixture;

b) mixing a plasticizer and water to form a liquid mixture;

c) heating the liquid mixture to a temperature of from about 75°C to about 90°C;

d) adding the dry mixture to the heated mixture with stirring to form a dispersion;

and

- e) heating the dispersion with stirring to a temperature of from about 85°C to about 95°C to form a uniform dispersion.
70. (Amended) A capsule formed with the ribbon made by the method of claim 63.
71. (Amended) A capsule formed with the ribbon made by the method of claim 65.
72. (Amended) A capsule formed with the extruded uniform dispersion made by the method of claim 68.
76. (Amended) A method for preparing a film-forming composition comprising:
- a) adding a mixture of iota carrageenan in an amount of from about 1% to about 15% by weight of the composition, kappa carrageenan in an amount less than 100% by weight of the iota carrageenan, a bulking agent in a ratio of bulking agent to total carrageenan of from about 1:1 to about 20:1, a plasticizer and water to an extruder;
  - b) forming a uniform dispersion of the mixture.
77. (Amended) The method of claim 76, wherein the mixture of iota carrageenan, kappa carrageenan, bulking agent, plasticizer and water are pre-mixed before adding them to the extruder.
84. (Amended) A ribbon comprising iota carrageenan, kappa carrageenan in an amount less than 100% by weight of the iota carrageenan, a bulking agent, a plasticizer and water, having a moisture content of between about 5% and about 20%, a tensile strength at rupture between about 5 N and about 40 N, an extensibility at rupture from about 20 mm to about 80 mm, and a viscosity from about 100 cP to about 1200 cP.